

CLAIMS

What is claimed is:

- 5 1. A patient screening method, comprising:
 delivering a pacing stimulus to a heart of a patient using one or more
 surface electrodes, the pacing stimulus delivered at a surface pacing level; and
 determining that the patient is not a candidate for implantation of a
 subcutaneous defibrillation system if the surface pacing level needed to capture the
10 patient's heart is beyond a predetermined level.
2. The method of claim 1, wherein the surface pacing level corresponds to
 a subcutaneous defibrillation energy level.
- 15 3. The method of claim 1, wherein the patient candidacy determination is
 based at least in part on a pre-established proportionality relationship between the
 surface pacing level and a subcutaneous defibrillation level.
4. The method of claim 1, wherein delivering the pacing stimulus comprises
20 positioning the one or more surface electrodes within one or more pre-determined
 thoracic regions relative to the patient's heart.
5. The method of claim 4, wherein the one or more predetermined thoracic
 regions define regions where a proportionality relationship between the surface pacing
25 level and a subcutaneous defibrillation energy level is operative.

6. The method of claim 1, wherein the predetermined level corresponds to a level of subcutaneous defibrillation energy above which the subcutaneous defibrillation system is not suited to deliver.

5 7. The method of claim 1, further comprising determining that the patient is a candidate for implantation of the subcutaneous defibrillation system if the surface pacing level needed to capture the patient's heart is within an acceptance level.

10 8. The method of claim 1, further comprising stratifying the patient for implantation of the subcutaneous defibrillation system using surface defibrillation tests without subjecting the patient to surgery.

15 9. The method of claim 8, further comprising defibrillation testing the patient using a cardiac defibrillation stimulus delivered at a surface defibrillation level if the surface pacing level needed to capture the patient's heart is beyond the acceptance level and does not exceed the predetermined limit.

20 10. The method of claim 9, wherein the subcutaneous defibrillation system is configured to deliver a defibrillation therapy at a subcutaneous defibrillation energy level equal to or greater than the surface defibrillation level.

11. A patient screening method, comprising:
locating at least two surface electrodes on a thorax of a patient;
determining a surface pacing threshold for effecting cardiac capture using the
25 at least two surface electrodes; and
determining if the patient is a candidate for implantation of a subcutaneous defibrillation system based on the surface pacing threshold.

12. The method of claim 11, further comprising;
relocating at least one of the plurality of surface electrodes on the thorax of the
patient;

after relocating, detecting a second surface pacing threshold; and
5 selecting a particular surface electrode location using the first and second
surface pacing thresholds.

13. The method of claim 12, wherein selecting the particular surface
electrode location comprises selecting a location corresponding to a location suitable
10 for implantation of a subcutaneous cardiac stimulation electrode.

14. The method of claim 12, further comprising implanting the subcutaneous
cardiac stimulation electrode at the selected location.

15 15. The method of claim 11, wherein locating the at least two surface
electrodes comprises locating an array of surface electrode elements on the patient's
thorax, and selecting the particular surface electrode location comprises scanning the
array of surface electrode elements to determine their associated surface pacing
thresholds.

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16. The method of claim 15, wherein the particular surface electrode location
is associated with a surface electrode element of the array that has a lowest
associated surface pacing threshold.

25 17. The method of claim 11, wherein locating the at least two surface
electrodes on the thorax of the patient comprises:

locating a first surface electrode of the at least two surface electrodes in
relation to a superior aspect of the patient's heart; and

locating a second surface electrode of the at least two surface electrodes in relation to an inferior aspect of the patient's heart.

18. The method of claim 11, wherein locating the at least two surface
5 electrodes on the thorax of the patient comprises locating at least one surface electrode substantially parallel to a ventricular free wall of the patient's heart.

19. The method of claim 11, wherein locating the at least two surface
electrodes on the thorax of the patient comprises locating at least one surface
10 electrode substantially parallel to a ventricular free wall of the patient's heart and extending a predetermined distance beyond the apex of the patient's heart.

20. The method of claim 11, further comprising inducing an arrhythmia in the
patient using the surface electrodes.

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21. The method of claim 20, further comprising delivering defibrillation
energy to the patient in response to the induced arrhythmia.

22. The method of claim 20, further comprising stratifying the patient for
20 implantation of one of a plurality of subcutaneous defibrillation systems based at least in part on a defibrillation level that terminates the arrhythmia.

23. A system, comprising:
a pulse generator configured to deliver a pacing stimulus at a pacing
25 level;
detection circuitry;

a plurality of surface electrodes coupled to the pulse generator and to the detection circuitry, the plurality of surface electrodes configured for positioning on a thorax of a patient relative to the patient's heart;

a user interface; and

5 a controller coupled to the pulse generator, detection circuitry, and user interface, respectively, the controller determining suitability of the patient to receive a subcutaneous defibrillation device based at least in part on detection of capture or non-capture resulting from delivery of the pacing stimulus at the pacing level.

10 24. The system of claim 23, further comprising a housing, the plurality of surface electrodes electrically coupled to the pulse generator and detection circuitry through the housing.

15 25. The system of claim 23, further comprising a housing, the plurality of surface electrodes supported by the housing.

20 26. The system of claim 23, further comprising a housing, the pulse generator and detection circuitry provided in the housing, and the plurality of surface electrodes coupled to the housing.

27. The system of claim 23, further comprising a housing, the pulse generator, detection circuitry, and controller provided in the housing, respectively, and the plurality of surface electrodes coupled to the housing.

25 28. The system of claim 23, further comprising a housing, the pulse generator, detection circuitry, controller, and user interface support by the housing, respectively, and the plurality of surface electrodes coupled to the housing.

29. The system of claim 28, wherein the housing comprises a handle and is configured for hand-held portability.

5 30. The system of claim 23, wherein the controller is configured to operate cooperatively with the user interface to provide a user with an indication of the suitability of the patient to receive the subcutaneous defibrillation device.

31. The system of claim 23, wherein the user interface comprises a display.

10 32. The system of claim 23, wherein the controller determines patient suitability based at least in part on a pre-established proportionality relationship between the pacing level of the pacing stimulus and a subcutaneous defibrillation level.

15 33. The system of claim 23, wherein the controller determines that the patient is not suitable to receive the subcutaneous defibrillation device if the pacing level of the pacing stimulus needed to capture the patient's heart is beyond a predetermined level.

20 34. The system of claim 33, wherein the predetermined level corresponds to a level of subcutaneous defibrillation energy above which the subcutaneous defibrillation device is not suited to deliver.

25 35. The system of claim 33, wherein the controller determines that the patient is suitable to receive the subcutaneous defibrillation device if the pacing level of the pacing stimulus needed to capture the patient's heart is within an acceptance level.

36. The system of claim 33, wherein the controller stratifies the patient for receiving the subcutaneous defibrillation device if the pacing level of the pacing stimulus needed to capture the patient's heart is beyond an acceptance level and within a predetermined level.

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37. A system, comprising:

detection circuitry;

energy delivery circuitry;

a plurality of surface electrodes coupled to the detection and energy

10 delivery circuitry, the plurality of surface electrodes configured for positioning on a patient's thorax relative to the patient's heart;

means, coupled to the detection and energy delivery circuitry, for determining capture or non-capture in response to delivery of a surface pacing stimulus; and

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means, coupled to the capture determining means, for determining if the patient is a candidate for implantation of a subcutaneous defibrillation device based at least in part on the capture or non-capture determination.

38. The system of claim 37, wherein the patient candidacy determining
20 means uses a pre-established proportionality relationship between a level of the surface pacing stimulus and a subcutaneous defibrillation level.

39. The system of claim 37, further comprising means for displaying an
25 indication of whether or not the patient is a candidate for implantation of the subcutaneous defibrillation device.

40. The system of claim 37, further comprising means, coupled to the energy delivery circuitry, for inducing an arrhythmia.

41. The system of claim 40, further comprising means for delivering defibrillation energy to the patient in response to inducing the arrhythmia.

5 42. The system of claim 40, further comprising stratifying the patient for implantation of one of a plurality of subcutaneous defibrillation systems based at least in part on a defibrillation level that terminates the arrhythmia.

10 43. The system of claim 40, further comprising means for stratifying the patient for implantation of one of a plurality of subcutaneous defibrillation devices.

15 44. A patient screening method, comprising:
 providing at least a pair of surface electrodes situated on a support structure,
 the pair of surface electrodes comprising a first and second surface electrodes having
 a fixed spatial relationship relative to one another;
 locating the first surface electrode at a first location on a thorax of a patient;
 moving the support structure to locate the second surface electrode at a
 second location on the patient's thorax;
 determining a surface pacing threshold for effecting cardiac capture using the
20 first and second surface electrodes; and
 determining if the patient is a candidate for implantation of a subcutaneous
 defibrillation system based on the surface pacing threshold.

45. The method of claim 44, wherein:
the first surface electrode is located relative to an apex of the patient's heart; and

5 moving the support structure comprises rotating the support structure
relative to the first surface electrode location to position the second surface electrode
at the second location on the patient's thorax.

46. The method of claim 44, wherein the first surface electrode is located
relative to an apex of the patient's heart and the second surface electrode is located in
10 relation to a superior aspect of the patient's heart.

47. The method of claim 46, further comprising rotating the second surface
electrode relative to the first surface electrode location while maintaining the fixed
spatial relationship.

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48. The method of claim 44, wherein the first surface electrode is located in
relation to an inferior aspect of the patient's heart and the second surface electrode is
located in relation to a superior aspect of the patient's heart.

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49. The method of claim 44, further comprising inducing an arrhythmia in the
patient using the first and second surface electrodes.

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50. The method of claim 49, further comprising delivering defibrillation
energy to the patient in response to the induced arrhythmia.

51. The method of claim 49, further comprising stratifying the patient for
implantation of one of a plurality of subcutaneous defibrillation systems based at least
in part on a defibrillation level that terminates the arrhythmia.

52. The method of claim 44, further comprising relocating the first surface electrode and the second surface electrode to respective new locations on the thorax of the patient.

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53. The method of claim 52, wherein the respective new locations are associated with a lowest associated surface pacing threshold.

54. A patient stratification system, comprising:
an electrode support assembly;
a plurality of surface electrodes supported by the electrode support assembly and having a fixed spatial relationship relative to one another, the plurality of surface electrodes configured for positioning on a thorax of a patient relative to the patient's heart;

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a pulse generator coupled to the plurality of surface electrodes and configured to deliver a pacing stimulus at a pacing level and a defibrillation stimulus at a defibrillation level;

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detection circuitry coupled to the plurality of surface electrodes; and

a controller coupled to the pulse generator and detection circuitry, the controller determining suitability of the patient to receive a subcutaneous defibrillation device based at least in part on detection of capture or non-capture resulting from delivery of the pacing stimulus at the pacing level.

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55. The system of claim 54, wherein the controller determines patient suitability based at least in part on a pre-established proportionality relationship between the pacing level of the pacing stimulus and a subcutaneous defibrillation level.

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56. The system of claim 54, wherein the controller stratifies the patient for receiving the subcutaneous defibrillation device if the pacing level of the pacing stimulus needed to capture the patient's heart is beyond an acceptance level and within a predetermined level.

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57. The system of claim 54, wherein the controller stratifies the patient for receiving the subcutaneous defibrillation device based at least in part on inducing an arrhythmia in the patient and determining the defibrillation level that terminates the arrhythmia.